

Remarks

Reconsideration of this Application is respectfully requested. The remarks below indicate the reasons the foregoing claims are in condition for allowance. Additionally, these remarks address items raised by the Examiner in the Final Office Action.

Reconsideration of this Application is respectfully requested.

Claims 150-170 are pending in the application, with claims 150, 160 and 170 being the independent claims. Claims 1-149 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 150-153, 155-163 and 165-170 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 5,957,949 to Leonhardt *et al.* ("Leonhardt") in view of U.S. Pat. No. 6,264,691 to Gabbay ("Gabbay"). Applicants respectfully traverse.

Independent claim 150 recites, among other features, a "valve support having an axial length sufficient to extend, when implanted, *from a position of a native annulus . . . past the patient's coronary ostia, and into an ascending aorta.*" The valve support includes "a first section . . . configured to engage the native annulus; and a second section . . . configured to extend past the coronary ostia and into the ascending aorta." Independent claims 160 and 170 recite similar distinguishing features.

Leonhardt discloses a valve stent 20 that is implanted at the location of the mitral valve, the aortic valve, or in the aorta. (Leonhardt at col. 5, ll. 41-42; col. 9, l.63 to col. 10, l.30; FIGS. 2, 3, and 9D.) Valve stent 20 is radially compressible and deployable via a catheter. (Leonhardt at Abstract.) Valve stent 20 is configured to conform to the tissue immediately around the location of the mitral valve and/or aortic valve, or to bond to the aorta. (Leonhardt at col. 5, ll. 48-52; col. 9, l.63 to col. 10, l.30.) However, as recognized by the Examiner, "Leonhardt et al. is silent with respect to the length of the stent serving as the valve support." (Final Office Action at 4.)

The Examiner cites Gabbay for teaching "a stent supporting a heart valve where different stent lengths may be applied to the same heart valve structure and the stent's length would be sufficient to extend from the native annulus past the coronary ostia . . . for the purpose of giving the stent the length needed to properly support the tissue surrounding the heart valve." (*Id.* at 4-5.) The Examiner also states "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the length of the stent to extend from the annulus into the ascending aorta in order to construct the stent so that it will provide additional support, as needed, to the tissue in the area where the prosthetic valve is being implanted." (*Id.* at 5.)

Further to the arguments of the previous Office Action response of August 9, 2011, Applicants contend that mere modification of the length of the stent in Leonhardt cannot render the present invention obvious.

The Examiner asserts that "it would have been an obvious matter of design choice to change the size of the stent" in Leonhardt "since such a modification would have involved a mere change in the size of a component." (Final Office Action at 5.) In the

present case, this logic, however, is flawed. The stent in Leonhardt is "*covered by and sutured to graft material.*" (Leonhardt at col. 5, l. 38 (emphasis added).) The graft material covering the stent is made of "*low porosity woven fabric, such as polyester or PTFE . . . [which] through its low porosity, creates the one-way fluid passage when sutured to the cylindrical form of [the] stent.*" (*Id.* at col. 5, ll. 54-59 (emphasis added).) Such a device, if extended "from a position of a native valve . . . past the patient's coronary ostia, and into an ascending aorta," as claimed, could prevent blood from reaching the coronary ostia. As stated in the previous Office Action reply, blockage of the coronary arteries can lead to rapid death of a patient, as discovered by Dr. Andersen in his early work with implanted heart valves. (See H.R. Andersen *et al.*, *Transluminal Implantation of Artificial Heart Valves. Description of a New Expandable Aortic Valve and Initial Results with Implantation by Catheter Technique in closed Chest Pigs*, 13 *European Heart J.* 704, 707 (1992) (noting that the coronary arteries were obstructed in pig no. 3, which only survived 15 minutes after implantation)). Thus, merely modifying the length of Leonhardt would not be obvious. To achieve the claimed configurations, which, for example, can reduce the risk that the ostia are occluded, *see, e.g.*, paragraph 142 of the as-filed specification, modifications well beyond a mere resizing of Leonhardt are required.

Thus, for at least the foregoing reasons, Applicants respectfully request that the rejection of independent claims 150, 160, and 170 under 35 U.S.C. § 103(a), and claims 150-153, 155-163 and 165-169, which depend from claims 150 and 160, be reconsidered and withdrawn.

Claims 154 and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt in view of Gabbay and further in view of U.S. Pat. No. 5,104,404 to Wolff ("Wolff"). Applicants respectfully traverse.

In light of the remarks above, it would not have been obvious to modify the length of the stent in Leonhardt in view of Gabbay. Wolff does not cure the deficiencies of Leonhardt and Gabbay. The Examiner cites Wolff as teaching "a stent constructed from multiple wires . . . for the purpose of allowing greater flexibility in the shape of the stent during its construction." (Final Office Action at 5.) Without acquiescing to the propriety of the rejection, Wolff does not disclose a valve support extending from a position of a native annulus past the patient's coronary ostia and into the ascending aorta. Therefore, Applicants respectfully request that the rejection of claims 154 and 164 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Reply is respectfully requested. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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